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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,671	12/10/2001	Otfried Kistner	V-262.00	2215

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EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/006,671	Applicant(s) KISTNER ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7-9,11,14-17 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7-9, 11, 14-17, 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed April 12, 2006 is acknowledged and entered. Claims 1, 2, 4, 7-9, 11, 14-17 and 27-31 remain pending and under examination.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 2, 4, 7-9, 11, 14-17 and 27-31 under 35 U.S.C., 103(a) as unpatentable over Dubensky Jr. *et al.* (5,789,245, "Dubensky") in view of Yu *et al.* (reference AM from IDS, "Yu"), is maintained for reasons of record. The claims are drawn to a method for producing purified Ross River Virus (RRV) antigen/immunogenic compositions comprising the steps of infecting a cell culture with RRV, incubating the infected cell culture, harvesting the RRV produced, filtering through two filters and purifying the virus antigen. The first filter has a pore size of between about 0.3 and about 1.5 microns. The second filter has a pore size of between about 0.1 and about 0.5 microns. Claims 27-31 are drawn to limitations of the methods the first filter is based on a positively charged matrix and the second filter is based on a hydrophilic matrix. The method further comprises treating the filtered virus with a nucleic acid degrading agent. The teachings of Dubensky and Yu are of record.

Applicant's arguments have been carefully considered but fail to persuade withdrawal of the rejection. Applicant's substantive arguments are primarily directed to the following:

- Applicant argues that the Office has provided no evidence why a second filter of a pore size ob between 0.1 microns and 0.5 microns would be obvious in light of Dubensky and/or the alpha virus particle size of 0.04 microns.

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- In response to Applicant's argument, the motivation to adjust the size of the filters is optimization. While Dubensky does not suggest altering the size of the second filter to 0.5 microns, Dubensky suggests the purification of RRV vectors. One of ordinary skill in the art would have known the size of RRV and adjusted accordingly in order to separate from unwanted components. Optimization is a process of improving what is already known. Modifying the filter sizes of Dubensky to arrive at a purer composition is optimization. Tweaking filter sizes to accommodate various dimensions is common in the art of virus purification. Lacking any evidence to the contrary, it would have been well within the skill of the ordinary artisan to adjust the filter size to better accommodate the virus size.
- Applicant asserts that the instantly claimed method results in a surprisingly pure RRV antigen *intermediate* through filtering without any substantial reduction in virus titer. Applicant points to the declaration of Otfried Kistner and Manfred Reiter, filed April 13, 2006, which the Office acknowledged and has been considered. An experiment is described in the declaration of a comparison between Applicant's method and Dubensky's method. RRV was cultured and purified according to the filter sizes indicated in the Table in the declaration.
 - The filters used according to Applicant's method included a 1.2 micron, followed by a 0.45 micron, resulting in 0.23 ngDNA/microgram Protein. Another filter combination used by Applicant includes a 1.2 micron filter, followed by a 0.45 micron, followed by a 0.2 micron filter. The result of that combination was 0.08 ngDNA/microgram Protein.

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- In the method of Dubensky, the RRV culture was filtered through a pore size of 0.8 microns, followed by a 0.65 micron filter, resulting in 1.62 ngDNA/microgram Protein. In another filter combination, RRV culture was filtered through a pore size of 0.8 microns, followed by a 0.65 micron filter, followed by a 0.2 micron filter, resulting in 0.73 ngDNA/microgram Protein.

In response to Applicant's arguments, and the declaration of Otfried Kistner and Manfred Reiter, filed April 13, 2006, the rejection is maintained for reasons of record. The Office recognizes that Applicant surprisingly discovered that the combination of filters (1.2 micron followed by 0.22 micron) resulted in a pure RRV intermediate composition. The claims encompass this embodiment, but the claims also encompass other embodiments, such as those described by Dubensky. One of ordinary skill in the art, optimizing Dubensky's method, would reasonably be considered to be practicing Applicant's invention. If Applicant claims the actual invention (1.2 micron followed by 0.22 micron filter), then the surprising result would be represented and the claims would be patentable over Dubensky. However, claiming filters outside the range of the surprising result reads on Dubensky's method. Therefore, the claims remain rejected.

Conclusion

No claim is allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 6/22/06

Stacy B. Chen
Primary Examiner
June 22, 2006